

(19)



(11)

EP 2 624 769 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
18.04.2018 Bulletin 2018/16

(51) Int Cl.:
A61B 17/04 ^(2006.01) **A61B 17/34** ^(2006.01)
A61B 17/16 ^(2006.01)

(21) Application number: **11770641.6**

(86) International application number:
PCT/US2011/054991

(22) Date of filing: **05.10.2011**

(87) International publication number:
WO 2012/048050 (12.04.2012 Gazette 2012/15)

(54) **A SYSTEM FOR USE IN TISSUE REPAIR**

SYSTEM ZUR VERWENDUNG BEI DER GEWEBEREPARATUR

SYSTÈME DESTINÉ À ÊTRE UTILISÉ POUR RÉPARER DES TISSUS

(84) Designated Contracting States:
**AL AT BE BG CH CY CZ DE DK EE ES FI FR GB
GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO
PL PT RO RS SE SI SK SM TR**

(30) Priority: **06.10.2010 US 390239 P**

(43) Date of publication of application:
14.08.2013 Bulletin 2013/33

(73) Proprietor: **Smith & Nephew, Inc.
Andover, MA 01810 (US)**

(72) Inventors:
• **SORENSEN, Peter Klindt
Salem, MA 01970 (US)**
• **KOSKI, Matthew Edwin
Westford, MA 01886 (US)**

- **TORRIE, Paul Alexander
Marblehead, MA 01945 (US)**
- **ELLIS, Daniel B.
Holliston, MA 01746 (US)**
- **SULLIVAN, James Joseph
Shrewsbury, MA 01545 (US)**

(74) Representative: **Smith & Nephew
Group Legal Department
PO Box 81
101 Hessle Road
Hull HU3 2BN (GB)**

(56) References cited:
WO-A1-2009/023034 US-A- 5 944 739
US-A1- 2008 188 854 US-A1- 2009 192 545

EP 2 624 769 B1

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a PCT International Patent Application claiming priority to US Patent Application Serial No. 61/390,239.

BACKGROUND

FIELD OF TECHNOLOGY

[0002] The present disclosure relates to tissue repair and, more specifically, to a system for use in tissue repair.

RELATED ART

[0003] Medical devices and methods for attaching soft tissue to bone have been developed. Of particular interest, especially in sports medicine procedures, are suture anchors. A suture anchor is typically inserted into and fixed in a bore hole drilled into a bone at a surgical repair site. Sutures are typically coupled to the anchor and are used to secure the soft tissue to the bone in order to effect the repair. For many repair procedures, accuracy in the placement of suture anchors in bone is required to achieve consistently positive surgical outcomes, requiring substantial skill on the part of the surgeon.

[0004] Accurate placement of bore holes and suture anchors can be particularly challenging when repair is performed arthroscopically, as both access to and visibility of an arthroscopic surgical site may be more limited than is the case with open surgical procedures. For example, accurately drilling bore holes and placing suture anchors into these holes, at certain joint areas of the body, can be difficult for even a very experienced surgeon. This is due to the delivery devices not being able to reach a preferred anchor delivery point, not being able to achieve the preferred anchor trajectory, or both. In addition to these access and visualization problems, current devices used in the delivery of suture anchors cannot withstand the forces imposed by new techniques. WO 2009/023034 discloses an anchor delivery system comprising:

- a cannulated guide;
- an obturator configured for insertion through the guide;
- a drill configured for insertion through the guide, the drill including a proximal portion and a distal portion, the drill proximal portion including a depth stop including flat sides, flat portions and the distal portion comprising a pointed end; and
- an anchor delivery tool configured for insertion through the guide, the anchor delivery tool including a handle and a shaft coupled to the handle, the shaft including a proximal portion, a distal portion having a smaller diameter than the proximal portion, and a

tip extending from the distal portion.

[0005] With the increasing popularity of arthroscopic repairs on the shoulder and hip, as well as repairs in other body joints including the ankle, knee, elbow, and foot, surgeons increasingly need to perform these procedures accurately and repeatably.

[0006] Accordingly, a need exists for devices and methods that provide for the accurate placement of suture anchors used in arthroscopic surgical procedures.

SUMMARY

[0007] The present invention relates to a system as defined in claim 1, for use in tissue repair.

[0008] Further embodiments of the invention are defined in the dependent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The accompanying drawings, which are incorporated in and form a part of the specification, illustrate the present disclosure and together with the written description serve to explain the principles, characteristics, and features of the disclosure. In the drawings:

Fig. 1 shows an isometric view of the guide.

Fig. 2 shows a side view of the guide of Fig. 1.

Fig. 3 shows an exploded view of the distal portion of the guide of Fig. 1.

Fig. 4 shows a side view of a first obturator.

Fig. 5 shows an isometric view of a second obturator.

Fig. 6 shows a side view of the obturator of Fig. 5.

Fig. 7 shows an exploded view of the distal portion of the obturator of Fig. 5.

Fig. 8 shows a side view of the drill.

Fig. 9 shows an exploded view of the distal portion of the drill of Fig. 8.

Fig. 10 shows an exploded view of the area of reduced diameter of the drill of Fig. 8.

Fig. 11 shows an isometric view of the anchor delivery tool.

Fig. 12 shows an exploded view of the distal portion of the anchor delivery tool of Fig. 11.

Fig. 13 shows a side view of the anchor delivery tool.

Fig. 14 shows an exploded view of the distal portion of the anchor delivery tool of Fig. 13.

DETAILED DESCRIPTION

[0010] The following description is merely exemplary in nature and is in no way intended to limit the disclosure, its application, or uses.

[0011] Figs. 1 -3 show a guide **10**. The guide **10** includes a cannulated handle **11** having a distal portion **11a**, a proximal portion **11b**, and an outer surface **11c**. The guide **10** also includes a shaft **12** coupled to the handle **11**. The shaft **12** includes a proximal portion **12a**

and distal portion **12b**. The proximal portion **12a** of the shaft **12** is coupled to the distal end **11a** of the handle **11**. The distal portion **12b** of the shaft **12** is angled relative to a longitudinal axis **L** of the guide **10**, which allows the surgeon to achieve the ideal insertion angle of the drill at a quicker rate, thereby reducing the potential of damage to cartilage and other tissue within the joint area, as will be further described below. The distal portion **12b** also includes at least one hole **12b'**. For the purposes of this disclosure, the distal portion **12b** includes a plurality of holes. The holes **12b'** are used during surgery to view the tissue anchor and, specifically the orientation of the tissue anchor, prior to inserting the anchor into bone, as will be further described below. The holes **12b'** may also be used to vent bone and other debris that may become located within the distal portion **12b** of the guide **12** during surgery, as will be further described below. An end **12c** of the shaft **12** includes a serrated edge **12c'** for facilitating maintenance of the guide **10** on the bone during surgery, thereby substantially reducing slippage of the guide **10** off of the bone, as will be further described below. Rather than a serrated edge **12c'**, the end **12c** may have other features known to one of skill that would help in maintaining the guide **10** on the bone and reduce slippage.

[0012] For the purposes of this disclosure, the handle **11** is manufactured from polymer material and via a molding or machining process. The shaft **12** is manufactured from metal material, such as stainless steel, and the holes **12b'** and serrated edge **12c'** are machined onto the shaft **12**. The distal portion **12b** of the guide **10** is bent or provided with an angle relative to the guide axis **L** via the use of a mandrel or other instrument that could be used to bend the shaft **12**. Other material and processes for making the handle **11** and shaft **12** are also within the scope of this disclosure. The handle **11** and shaft **12** are coupled together via a press-fit procedure. However, other manners of coupling are also within the scope of this disclosure.

[0013] Figs. 4-7 show examples of an obturator **20** for use with guide **10**. The obturator **20** includes a handle **21** and a shaft **22** coupled to the handle **21**. The shaft **22** includes a proximal portion **22a** coupled to the handle **21**, a distal portion **22b**, and a portion **22c** located between the proximal and distal portions **22a,22b** having a reduced diameter relative to the diameter of the proximal and distal portions **22a,22b**. The reduced diameter of portion **22c** allows the portion **22c** to bend when the shaft **22** is inserted through the guide **10** and the portion **22c** is located within the angled distal portion **12b**. Fig. 4 shows a first obturator **20** including a distal portion **22b** having a tapered, blunt end **22b'** and Figs. 5-7 show a second obturator **20** including a distal portion **22b** having a sharp end **22b'**. When the shaft **22** of the obturator **20** is located within the guide **10**, the end **22b'** extends through end **12c**, thereby reducing the possibility of the shaft end **12c**, and especially the serrated edge **12c'**, from catching onto tissue as the guide **10** is inserted into

the body, in the case of the obturator **20** having the blunt, tapered end **22b'**, and allowing for easier and quicker insertion of the guide **10** into the body, in the case of the obturator having the sharp end **22b'**, as will be further described below.

[0014] For the purposes of this disclosure, the handle **21** is made from polymer material and via a molding or machining process. The shaft **22** is made from metal and via a welding procedure. The proximal portion **22a**, distal portion **22b**, and portion **22c** are welded together to make the shaft **22**. However, a one-piece shaft is within the scope of this disclosure. The surface features of the distal portion **22b**, blunt, taper or sharp, pointed features, are made via a machining process. Other material and processes for making the handle **21** and shaft **22** are also within the scope of this disclosure.

[0015] Figs. 8-10 show a drill **30** for use with the guide **10**. The drill **30** includes a proximal portion **30a**, a distal portion **30b**, and a flexible portion **30c** located between the proximal and distal portions **30a,30b**. The proximal portion **30a** includes an end **30d** having flat portions **30d'** configured for coupling to a drill **30**, a depth stop **30e** having flat sides **30e'** for maintaining a location of the drill **30** while the drill **30** is sitting on a surgeon tray or table prior to use by the surgeon, and an area of reduced diameter **30f**. The area **30f** includes a laser weld mark **30g**, the purpose of which will be described below. The flexible portion **30c** extends between the area **30f** and the distal portion **30b**. When the drill **30** is located within the guide **10**, portion **30c** is located within the angled distal portion **12b** and is sufficiently flexible to bend along the angle of portion **12b**. The flexible portion **30c** includes an inner layer of spirally wound metal wires and an outer layer of spirally wound metal wires surrounding the inner layer. The inner layer also includes a through hole extending the length of the flexible portion **30c**. The distal portion **30b** includes helical threads **30h**, a pointed end **30i**, and a laser weld mark **30j**. When the drill **30** is located within the guide **10**, the end **30b** extends through end **12c**, thereby allowing the user to drill a hole in bone during surgery, as will be further described below.

[0016] For the purposes of this disclosure, the drill **30** is made from metal, such as stainless steel. The flat portions **30d',30e'** of the end **30d** and the depth stop **30e** may be machined onto the end **30d** and stop **30e**. The area of reduced diameter **30f** includes an inner wall having a diameter that is the same or similar to the diameter of the inner wall of the portion of the distal portion **30b** that is coupled to the flexible portion **30c**. The area of reduced diameter **30f** is made via a machining process.

[0017] The flexible portion **30c** is made via the use of a mandrel, which is removed from the through hole of the inner layer once the flexible portion **30c** is made. As mentioned above, the ends of the flexible portion **30c** are laser welded to the area **30f** and distal portion **30b**. The ends are inserted into the area **30f** and distal portion **30b** and then a laser is used to melt the metal material to the ends where the laser welds **30g,30j** are located in Figs.

9 and 10, thereby welding the area **30f** and the distal portion **30b** to the flexible portion **30c**. Coupling of the flexible portion **30c** to the area **30f** and distal portion **30b** in this manner reduces breakage or failure of the laser welds **30g,30j** due to the laser welds **30g,30j** being located in an area where there is the least amount of movement of the flexible portion **30c** during use of the drill **30**.

[0018] During use of the drill **30**, the depth stop **30e** abuts the handle **11**, thereby substantially reducing over-insertion of the distal portion **30b** into the bone, as will be further described below. The threads **30h** and pointed end **30i** on the distal portion **30b** are made via a machining process. The drill **30** and its components and features may be made from other materials and processes known to one of skill in the art.

[0019] Figs. 11-14 show an anchor delivery tool **40**. The tool **40** includes a shaft **41** and a handle **42** coupled to the shaft **41**. The shaft **41** includes a proximal portion **41a** and a distal portion **41b**. The distal portion **41b**, as more clearly shown in Fig. 12, includes an area of reduced diameter **43** and a tip **44** that extends from the distal portion **41b**. The area of reduced diameter **43** allows the shaft **41** to bend along the angled distal portion **12c** when the shaft **41** is inserted through the guide **10**. Prior to use, a suture anchor (**not shown**) is coupled to the tip **44**. The suture anchor (**not shown**) extends through end **12c** when the shaft **41** is disposed within the guide **10**. The shaft **41** also includes grooves **41'** for housing of suture extending from the anchor, as will be further described below.

[0020] The proximal portion **41a** of the shaft **41** is coupled to the handle **42**. The handle **42** includes a hub **42a**, a nose cone **48** coupled to the hub **42a**, and a knob **49** coupled to the hub **42a** and located between the nose cone **48** and the handle **42**. The handle **42** further includes two suture retaining features **42b**, or tabs, for retaining suture during surgery, as will be further described below, laterally extending ribs **42c** for maintaining a grip on the handle **42** while imparting axial compression during surgery, and a through passage **42d**. The nose cone **48** includes a flat distal portion **48a**, and a proximal portion **48b**. In addition, the nose cone **48** includes a slotted opening **48d** for housing suture during surgery, as will be further described below, and a bore **48e**. The knob **49** also includes laterally extending wings **49c**.

[0021] The handle **42** and shaft **41**, their components, and their method of use are more fully described in International Patent Application Publication WO 2009/023034 ('034 publication), which is incorporated herein by reference in its entirety. However, the area of reduced diameter **43** is made via a machining process or other process known to one of skill in the art. In addition, the suture anchor used with the device **40** and the manner in which it is used is the same suture anchor and method of use shown in the '034 publication.

[0022] The method of tissue repair via use of the system and its components is similar to the method of tissue repair shown and described in the '034 publication. The

method includes inserting the obturator through the guide, inserting the guide/obturator combination into the joint area such that the end of the guide shaft is engaged with bone, removing the obturator, inserting the drill through the guide and operating the drill to create a hole in the bone, removing the drill, inserting the shaft of the delivery device through the guide and inserting the anchor into the hole and removing the guide and delivery device. Subsequent to removal of the guide and delivery device, the soft tissue is located adjacent to the suture anchor and the suture may be pulled through the tissue and subsequently tied to fixate the tissue to the bone.

[0023] The breadth and scope of the present invention should not be limited by any of the above-described examples, but should be defined only in accordance with the following claims appended hereto.

Claims

1. A system for use in tissue repair comprising:

a cannulated guide (10);
 an obturator (20) configured for insertion through the guide;
 a drill (30) configured for insertion through the guide, the drill including a proximal portion (30a), a distal portion (30b), and a flexible portion (30c) located between the proximal and distal portions, the drill proximal portion including a depth stop (30e), an end (30d) comprising flat portions (30d') configured for coupling to a drill, and an area of reduced diameter (30f), the depth stop including flat sides, and the area of reduced diameter (30f) including a laser weld mark (30g), the distal portion including helical threads (30h), a pointed end (30i), and a laser weld mark (30j), ends of the flexible portion attached to the area of reduced diameter and the distal portion via the laser welds, wherein the flexible portion (30c) has a diameter that is smaller than a diameter of the area of reduced diameter (30f) and a diameter of the distal portion (30b); and
 an anchor delivery tool (40) configured for insertion through the guide, the anchor delivery tool including a handle (42) and a shaft (41) coupled to the handle, the shaft including a proximal portion (41a), a distal portion (41b) having a smaller diameter (43) than the proximal portion, and a tip (44) extending from the distal portion (41b).

2. The system of claim 1 wherein the guide includes a handle (11) and a shaft (12) coupled to the handle.

3. The system of claim 2 wherein the shaft includes a distal portion (12b) angled relative to a longitudinal axis of the shaft.

4. The system of claim 3 wherein the distal portion (12b) includes at least one hole (12b').
5. The system of claim 3 wherein the distal portion (12b) includes an end having a serrated edge (12c'). 5
6. The system of any one of the preceding claims wherein the obturator (20) includes a handle (21) and a shaft (22) and wherein the shaft includes a proximal portion (22a), a distal portion (22b), and a portion of reduced diameter (22c) located between the proximal portion and the distal portion. 10
7. The system of claim 6 wherein the distal portion (22b) of the obturator (20) includes a blunt end. 15
8. The system of claim 6 wherein the distal portion (22b) of the obturator (20) includes a sharp end.
9. The system of claim 6 wherein the portion of reduced diameter (22c) of the obturator (20) is flexible relative to the proximal portion (22a) of the obturator (20). 20
10. The system of any of the preceding claims wherein the distal portion (41b) of the anchor delivery tool is flexible relative to the proximal portion (41a) of the anchor delivery tool. 25

Patentansprüche

1. Ein System zur Verwendung bei der Gewebereparatur, das Folgendes beinhaltet:

eine kanülierte Führung (10); 35
 einen Obturator (20), der zum Einführen durch die Führung konfiguriert ist;
 einen Bohrer (30), der zum Einführen durch die Führung konfiguriert ist, wobei der Bohrer einen proximalen Abschnitt (30a), einen distalen Abschnitt (30b) und einen zwischen dem proximalen und distalen Abschnitt befindlichen flexiblen Abschnitt (30c) umfasst, wobei der proximale Abschnitt des Bohrers einen Tiefenanschlag (30e), ein Ende (30d), das flache Abschnitte (30d') beinhaltet, die zum Koppeln an einen Bohrer konfiguriert sind, und einen Bereich mit verringertem Durchmesser (30f) umfasst, wobei der Tiefenanschlag flache Seiten umfasst und der Bereich mit verringertem Durchmesser (30f) eine Laserschweißnahtmarkierung (30g) umfasst, wobei der distale Abschnitt Schraubengewinde (30h), ein spitzes Ende (30i) und eine Laserschweißnahtmarkierung (30j) umfasst, wobei Enden des flexiblen Abschnitts über die Laserschweißnähte an dem Bereich mit verringertem Durchmesser und dem distalen Abschnitt befestigt sind, wobei der flexible Abschnitt (30c) 50

einen Durchmesser aufweist, der kleiner ist als ein Durchmesser des Bereichs mit verringertem Durchmesser (30f) und ein Durchmesser des distalen Abschnitts (30b); und
 ein Ankerzuführwerkzeug (40), das zum Einführen durch die Führung konfiguriert ist, wobei das Ankerzuführwerkzeug einen Griff (42) und einen an den Griff gekoppelten Schaft (41) umfasst, wobei der Schaft einen proximalen Abschnitt (41a), einen distalen Abschnitt (41b) mit einem kleineren Durchmesser (43) als der proximale Abschnitt und eine Spitze (44), die sich von dem distalen Abschnitt (41b) erstreckt, umfasst.

2. System gemäß Anspruch 1, wobei die Führung einen Griff (11) und einen an den Griff gekoppelten Schaft (12) umfasst.
3. System gemäß Anspruch 2, wobei der Schaft einen relativ zu einer Längsachse des Schafts abgewinkelten distalen Abschnitt (12b) umfasst.
4. System gemäß Anspruch 3, wobei der distale Abschnitt (12b) mindestens ein Loch (12b') umfasst.
5. System gemäß Anspruch 3, wobei der distale Abschnitt (12b) ein eine gezahnte Kante (12c') aufweisendes Ende umfasst.
6. System gemäß einem der vorhergehenden Ansprüche, wobei der Obturator (20) einen Griff (21) und einen Schaft (22) umfasst und wobei der Schaft einen proximalen Abschnitt (22a), einen distalen Abschnitt (22b) und einen Abschnitt mit verringertem Durchmesser (22c), der zwischen dem proximalen Abschnitt und dem distalen Abschnitt befindlich ist, umfasst. 30
7. System gemäß Anspruch 6, wobei der distale Abschnitt (22b) des Obturators (20) ein stumpfes Ende umfasst. 40
8. System gemäß Anspruch 6, wobei der distale Abschnitt (22b) des Obturators (20) ein scharfes Ende umfasst. 45
9. System gemäß Anspruch 6, wobei der Abschnitt mit verringertem Durchmesser (22c) des Obturators (20) relativ zu dem proximalen Abschnitt (22a) des Obturators (20) flexibel ist. 50
10. System gemäß einem der vorhergehenden Ansprüche, wobei der distale Abschnitt (41b) des Ankerzuführwerkzeugs relativ zu dem proximalen Abschnitt (41a) des Ankerzuführwerkzeugs flexibel ist. 55

Revendications

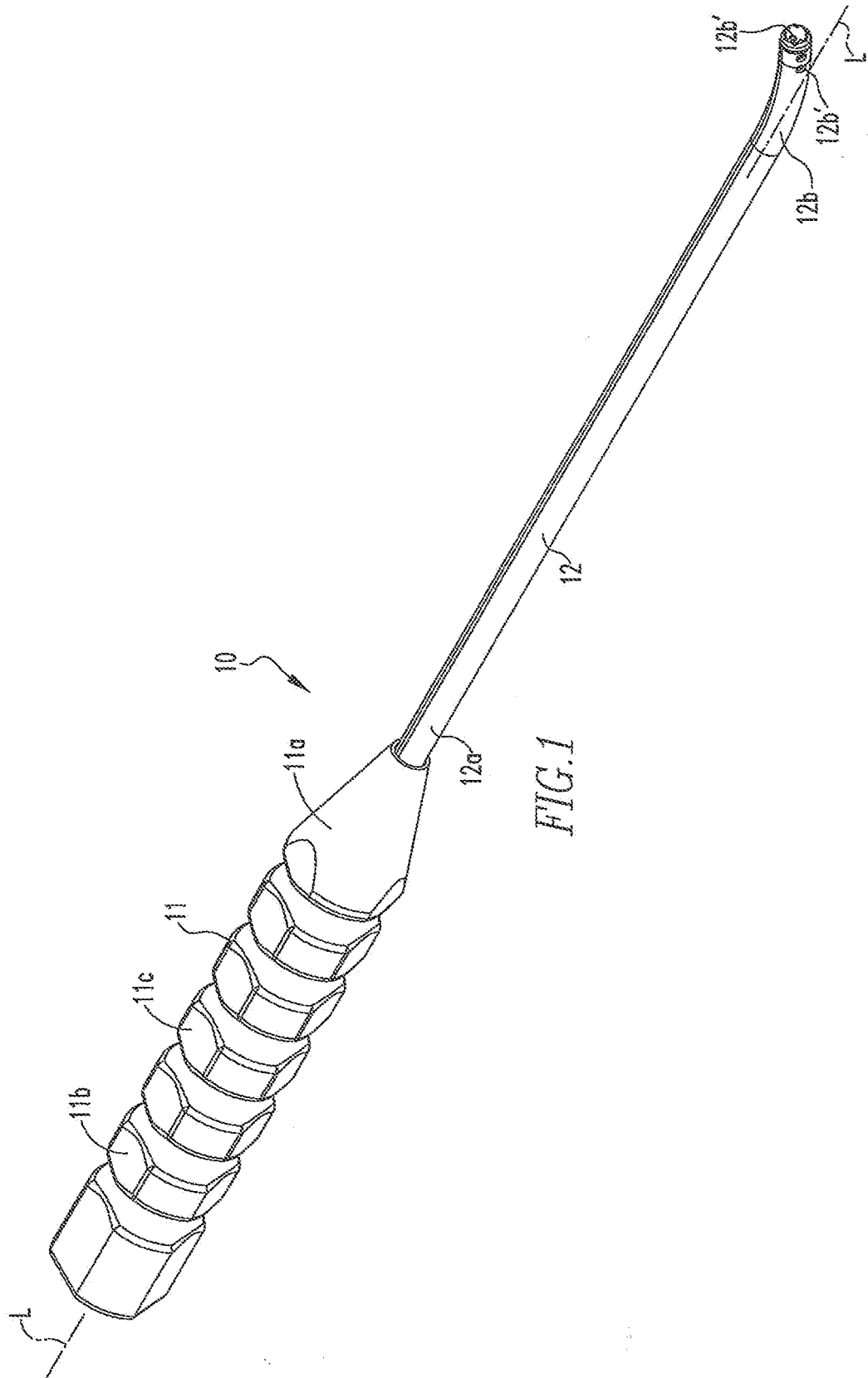
1. Un système destiné à être utilisé dans la réparation tissulaire comprenant :

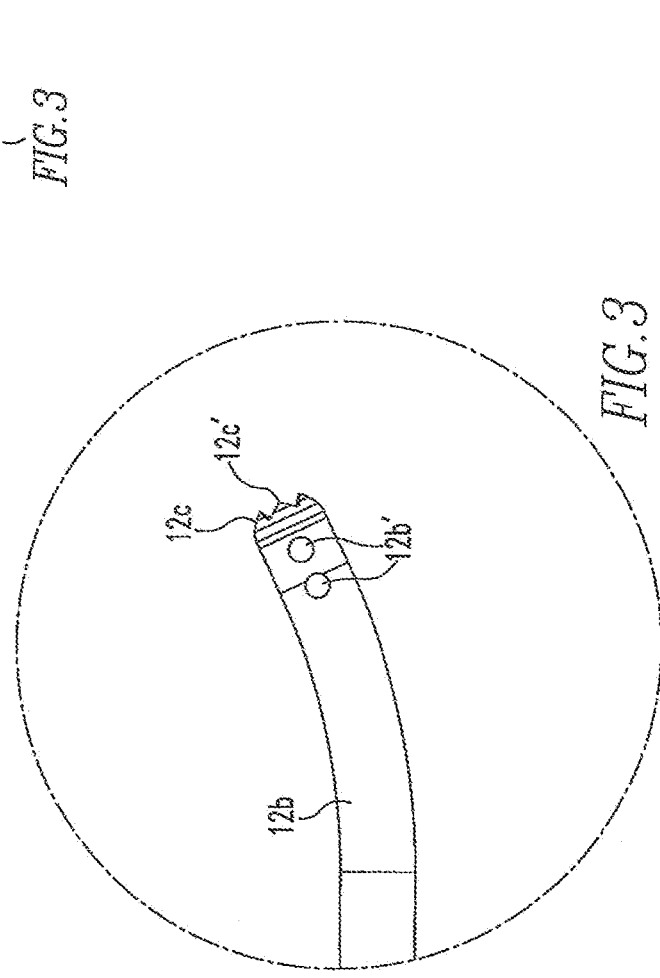
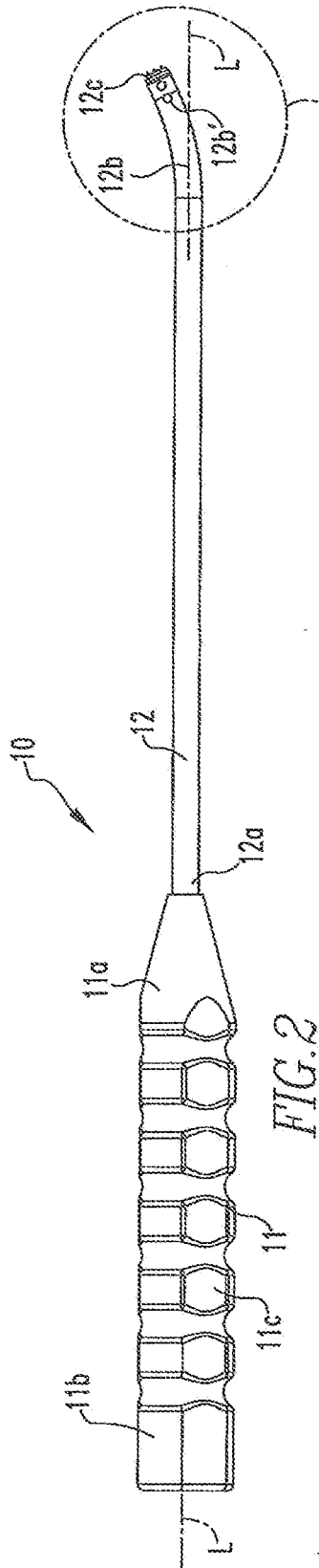
un guide canulé (10) ;
 un obturateur (20) configuré pour être inséré dans le guide ;
 un foret (30) configuré pour être inséré dans le guide, le foret incluant une portion proximale (30a), une portion distale (30b), et une portion flexible (30c) située entre les portions proximale et distale, la portion proximale de foret incluant une butée de profondeur (30e), une extrémité (30d) comprenant des portions plates (30d') configurées pour s'accoupler à un foret, et une zone de diamètre réduit (30f), la butée de profondeur incluant des côtés plats, et la zone de diamètre réduit (30f) incluant une marque de soudure au laser (30g), la portion distale incluant des filets hélicoïdaux (30h), une extrémité pointue (30i), et une marque de soudure au laser (30j), des extrémités de la portion flexible étant attachées à la zone de diamètre réduit et à la portion distale par le biais des soudures au laser, la portion flexible (30c) ayant un diamètre qui est plus petit qu'un diamètre de la zone de diamètre réduit (30f) et un diamètre de la portion distale (30b) ; et
 un outil de livraison d'ancre (40) configuré pour être inséré dans le guide, l'outil de livraison d'ancre incluant une poignée (42) et un arbre (41) couplé à la poignée, l'arbre incluant une portion proximale (41a), une portion distale (41b) ayant un diamètre plus petit (43) que la portion proximale, et un bout (44) s'étendant depuis la portion distale (41b).

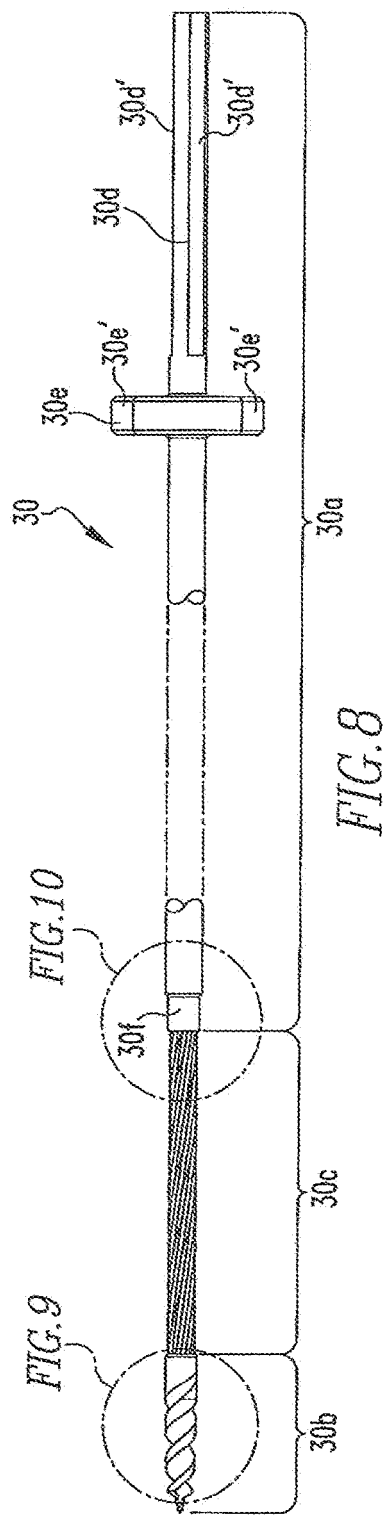
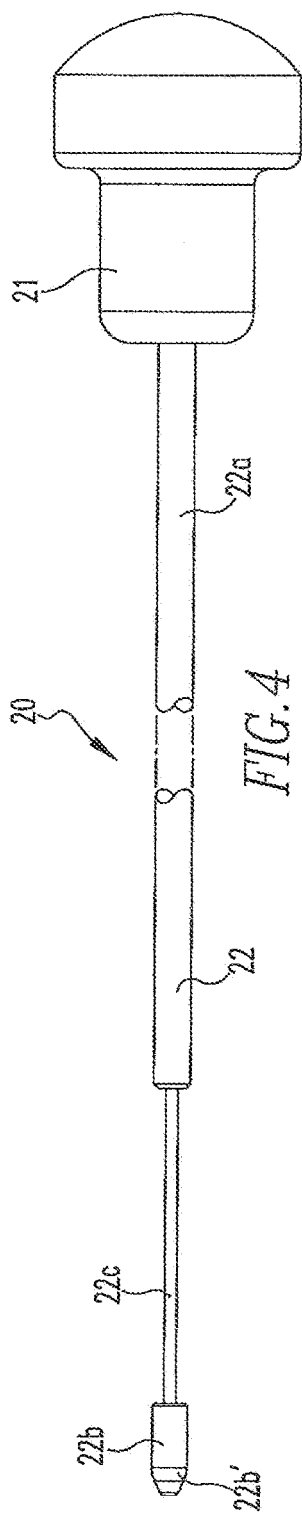
2. Le système de la revendication 1 dans lequel le guide inclut une poignée (11) et un arbre (12) couplé à la poignée.
3. Le système de la revendication 2 dans lequel l'arbre inclut une portion distale (12b) en biais relativement à un axe longitudinal de l'arbre.
4. Le système de la revendication 3 dans lequel la portion distale (12b) inclut au moins un trou (12b').
5. Le système de la revendication 3 dans lequel la portion distale (12b) inclut une extrémité ayant un bord dentelé (12c').
6. Le système de n'importe laquelle des revendications précédentes dans lequel l'obturateur (20) inclut une poignée (21) et un arbre (22) et dans lequel l'arbre inclut une portion proximale (22a), une portion distale (22b), et une portion de diamètre réduit (22c)

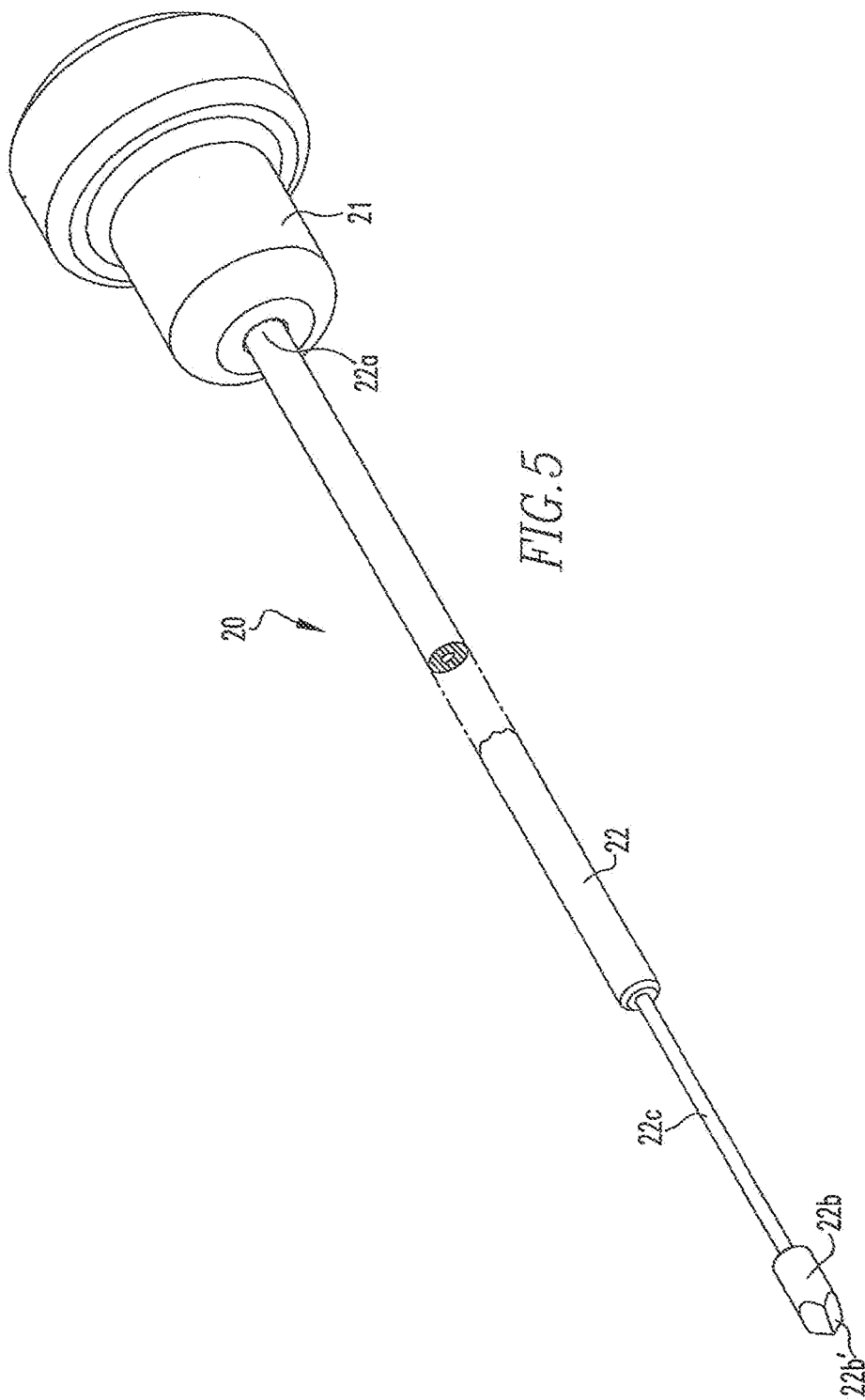
située entre la portion proximale et la portion distale.

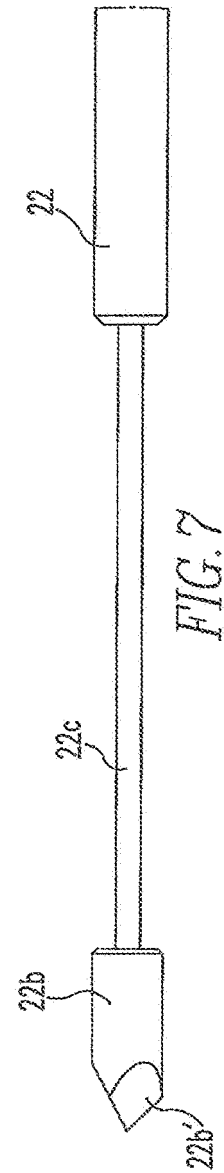
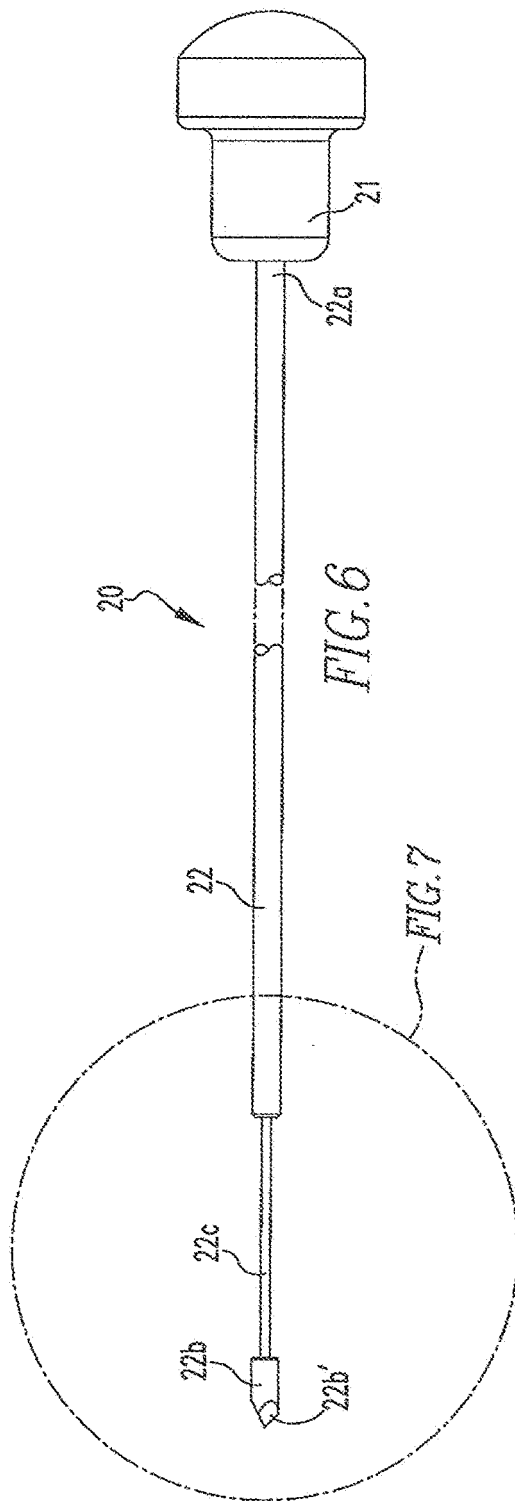
7. Le système de la revendication 6 dans lequel la portion distale (22b) de l'obturateur (20) inclut une extrémité moussée.
8. Le système de la revendication 6 dans lequel la portion distale (22b) de l'obturateur (20) inclut une extrémité aiguisée.
9. Le système de la revendication 6 dans lequel la portion de diamètre réduit (22c) de l'obturateur (20) est souple relativement à la portion proximale (22a) de l'obturateur (20).
10. Le système de n'importe lesquelles des revendications précédentes dans lequel la portion distale (41b) de l'outil de livraison d'ancre est flexible relativement à la portion proximale (41a) de l'outil de livraison d'ancre.











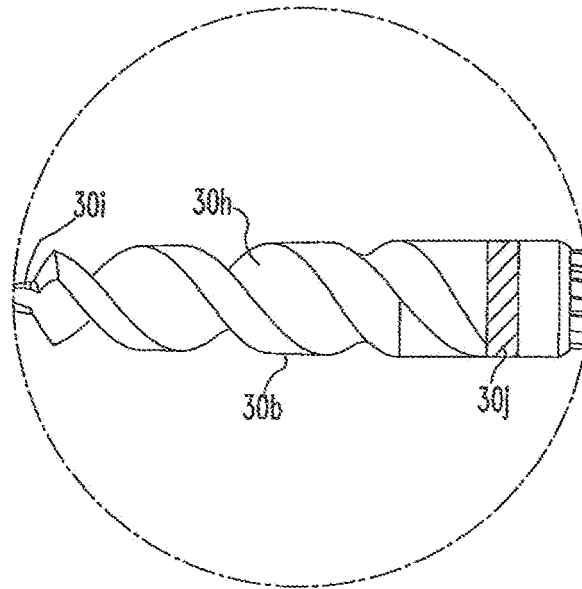


FIG. 9

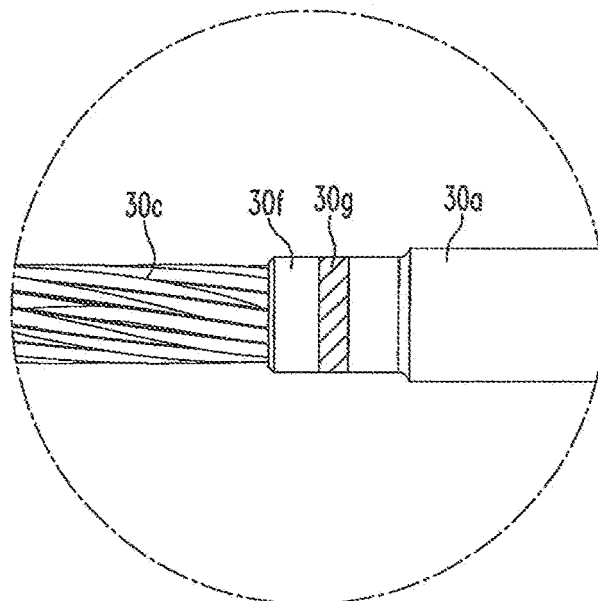
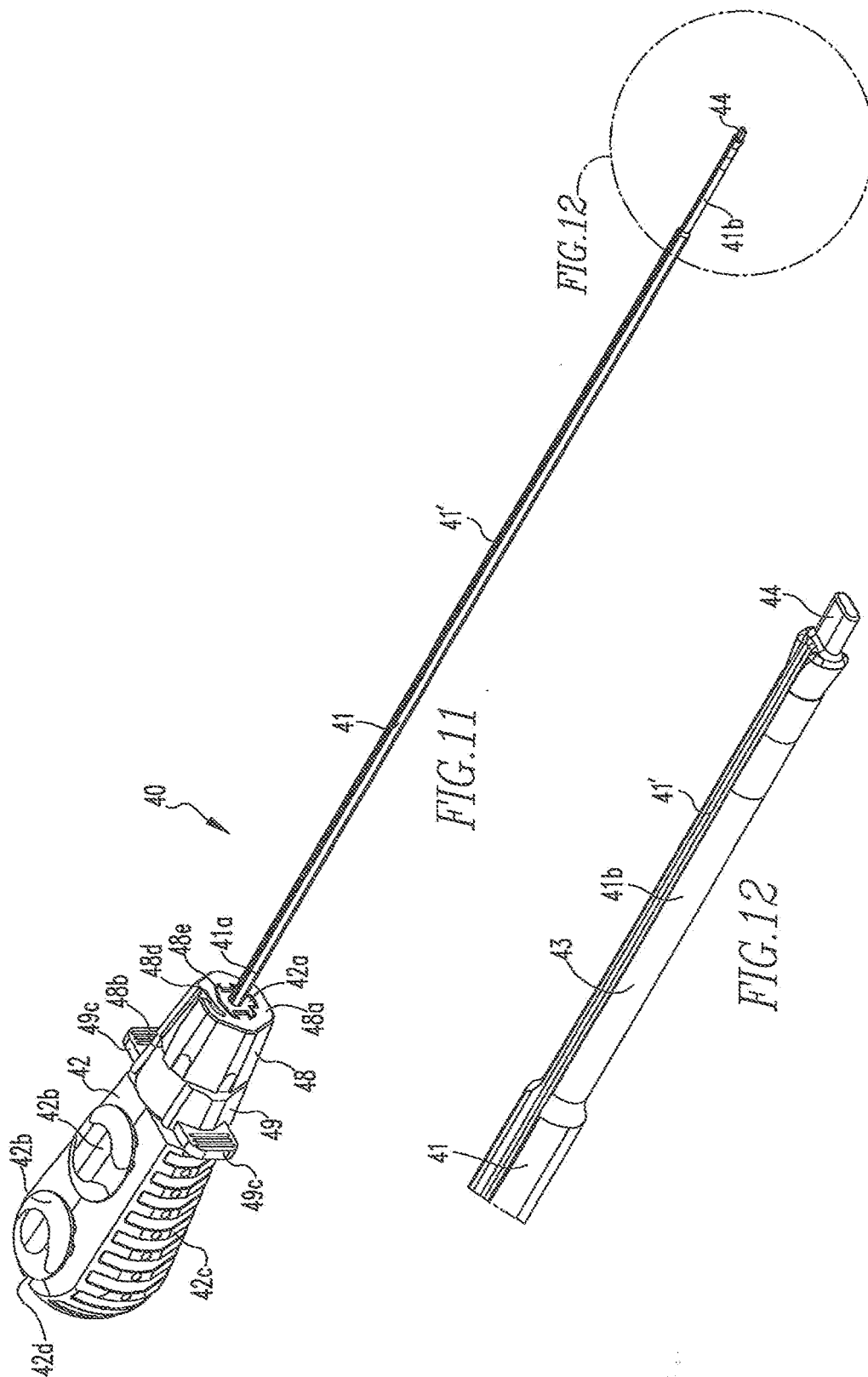
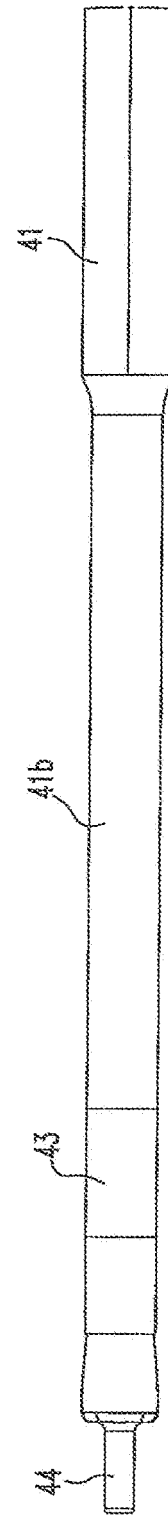
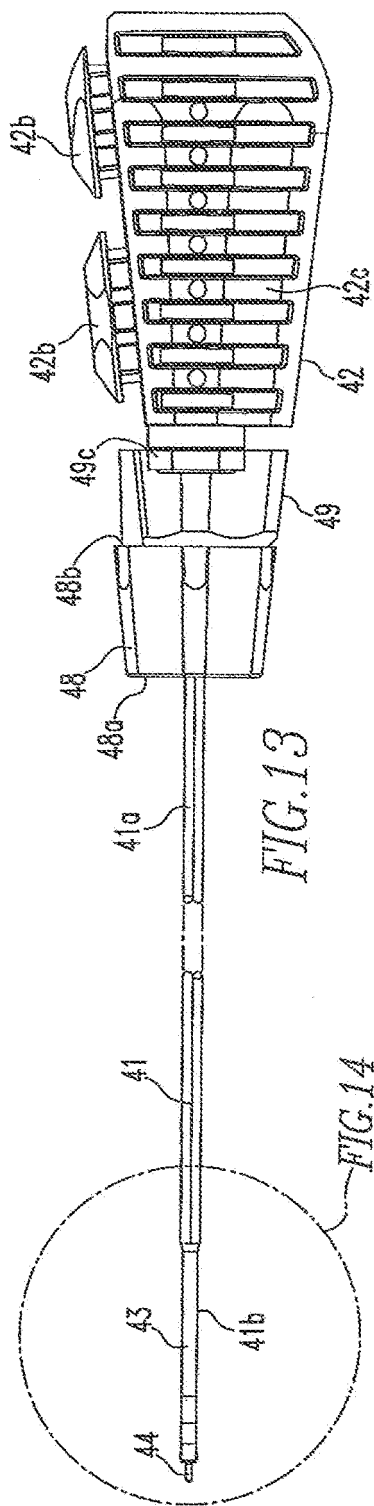


FIG. 10





REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 61390239 PCT [0001]
- WO 2009023034 A [0004] [0021]